

EXHIBIT H

To: Kevin Thurm

Subject: Medicare Payments for Drugs Using Department of Justice Data--
INFORMATION

This memo is to update you on the status of our efforts to revise Medicare payments for drugs using new average wholesale price data compiled by the Department of Justice (DOJ). Medicare payment is based on the lower of the billed charge or 95 percent of the average wholesale price.

On May 31st, the Secretary wrote to Congressman Bliley (and I wrote to Congressman Stark) indicating that we would use the new DOJ data which were from wholesale catalogs that DOJ has obtained. On May 1, 2000, these data were made available to State Medicaid programs, some of which have implemented them while others have not.

The Secretary's letter indicated that in June we would send the DOJ data to carriers for them to use for their next quarterly update of Medicare drug allowances which will become effective October 1, 2000. We also indicated that we could not require carriers to use these new data and that we would meet with physician groups to review payment rates for chemotherapy administration to ensure that those payments are adequate as we reduce payments for drugs.

We have met with oncology physicians and also with a hemophilia drug supplier. We also have received a revised opinion from OGC indicating that we can require carriers to use the DOJ data because it is characterized by DOJ as more accurately reflecting average wholesale prices. We have also further analyzed the potential impact.

Some 14 of the 51 drugs on the DOJ list are oncology drugs. These drugs represent about 17 percent of Medicare spending for drugs on the DOJ list and 26 percent of the savings. The reductions for oncology drugs would average 75 percent.

Oncology physicians indicate that drug mark-ups compensate for what they believe are inadequate Medicare payments for chemotherapy administration. About 67 percent of oncologists' Medicare revenues are from drugs and implementation of the DOJ data would result in a 7 percent reduction in their Medicare revenues. Therefore, we are reviewing our payment policies (e.g., payment for multiple "pushes" on the same day) for chemotherapy administration. However, any policy changes could not be implemented before January 1, 2001 (through the physician fee schedule final rule this November).

We already have received letters from physicians and cancer patients that use of the DOJ data would limit access to cancer care and cause physicians to send patients to hospital

F

HHD809-0008

outpatient departments for treatment. We believe that the cancer community will unleash a significant grass-roots effort to stop implementation of the use of the DOJ data if we proceed without a more comprehensive approach to the range of Medicare payment policies affecting cancer care in physician offices.

Similarly, we have met with a hemophilia supplier, and believe that their views reflect the views of the entire industry. Hemophilia drugs are furnished by suppliers to patients either in their home or through hemophilia centers. Medicare does not make payments to hemophilia centers or for suppliers to furnish drugs to home patients. As a result, suppliers use drug mark-ups to cover these costs. Suppliers argue that they will not be able to furnish services to Medicare patients if the DOJ data are implemented. The reduction for hemophilia drugs is about 30 percent. The three hemophilia drugs on the DOJ list represent about 5 percent of Medicare spending for drugs on the list and about 5 percent of the savings.

Of the remaining 34 drugs, 2 are furnished by urologists (the largest being lupron), 4 are inhalation drugs furnished by durable medical equipment suppliers (the largest being albuterol), 2 are end-stage renal disease drugs (other than EPO) and 20 drugs are steroids, tranquilizers, antibiotics, impotence-related, AIDS-related, etc. Finally, 2 of the 51 drugs are not covered under the Medicare drug benefit (and thus not paid under the average wholesale price) and another 4 have no Medicare billing codes. Please see the attached chart for the breakdown.

We plan to require carriers to implement the new, more accurate DOJ average wholesale price data for all but the 14 oncology and 3 hemophilia drugs. Requiring carriers to use the data would be a step further than indicated in the Biley and Stark letters where we indicated that we would send the data to carriers for them to consider when they determined average wholesale prices. This would also implement the policy for the drugs representing the bulk of Medicare spending for drugs on the DOJ list (77 percent) and achieve the bulk of savings (69 percent). We will also use the DOJ price data for payment made under the outpatient hospital prospective payment system. (About half of the drugs on the DOJ list are also reimbursed separately under the outpatient PPS.)

We will shortly send data on all the DOJ drugs to carriers in two files, one to implement for October 1, 2000, the other to hold for implementation at a future date. Before implementing the DOJ data for oncology drugs we will comprehensively review a series of Medicare policies affecting cancer treatment in physician offices. Similarly, we before implementing the DOJ data for hemophilia drugs we will review issues about payment for their delivery. The date for implementation for the oncology and hemophilia drugs would depend on our review and analysis of the special situations for those drugs.

Attachment

L
HHD809-0009

TO: Kevin Thurm
Deputy Secretary
Through: ES _____
COS _____

FROM: Michael M. Hash
Deputy Administrator

RE: Medicare Payments for Drugs Using Department of Justice Data - INFORMATION

The Health Care Financing Administration (HCFA) is moving ahead to implement revisions to Medicare payments for drugs by using new average wholesale price data compiled by the Department of Justice (DOJ). The purpose of this memo is to update you regarding our progress.

Background

By law, Medicare payment is based either on the lower of the billed charge or 95 percent of the average wholesale price (AWP). Medicare contractors obtain the AWP data from one of several sources, primarily the *Red Book*. For years, many analysts have believed that the drug manufacturers have artificially inflated the AWP data. In fact, earlier this year, DOJ compiled a new set of AWP for 51 drugs as part of a lawsuit. In May 2000, these data were made available to State Medicaid programs, some of which have implemented them while others have not.

Following several inquiries from Congress, the Secretary announced in a letter to Congressman Bliley that HCFA would provide the DOJ data to our contractors. The HCFA Administrator wrote a similar letter to Congressman Stark (attached). More specifically, the Secretary's letter indicated that HCFA, by the end of June, would send the DOJ data to carriers for them to use for their next quarterly update of Medicare drug allowances which will become effective October 1, 2000. We also indicated that we could not require carriers to use these new data. Finally, in an effort to ensure access and quality, the letter stated that HCFA would meet with physician groups to review the adequacy of the reduced payment rates for chemotherapy administration.

Actions Taken

HCFA met with oncology physicians. Fourteen of the 51 drugs on the DOJ list are oncology drugs. Oncology physicians indicate that drug mark-ups compensate for what they believe are inadequate Medicare payments for chemotherapy administration. The reimbursement payment reductions for oncology drugs would average 75 percent. About 67 percent of oncologists' Medicare revenues are from drugs and implementation of the DOJ data would result in a 7 percent reduction in their Medicare revenues. Therefore, we are reviewing our payment policies (e.g., payment for multiple "pushes" on the same day) for chemotherapy administration. However, any policy changes could not be implemented before January 1, 2001 (through the physician fee schedule final rule). Based on further analysis, it is now clear that these drugs represent about 17 percent of Medicare spending

F

HHD809-0010

for drugs on the DOJ list and 26 percent of the savings. (Please see attached chart.) We have already received letters from physicians and cancer patients that use of the DOJ data would limit access to cancer care and cause physicians to send patients to hospital outpatient departments for treatment. We are aware that the cancer community has launched a significant effort to stop implementation of the DOJ data.

Similarly, we have met with a hemophilia supplier. We believe that their views reflect the views of the larger industry. Hemophilia drugs are furnished by suppliers to patients either in their home or through hemophilia centers. Medicare does not make payments to hemophilia centers or for suppliers to furnish drugs to home patients. As a result, suppliers use drug mark-ups to cover these costs. Suppliers argue that they will not be able to furnish services to Medicare patients if the DOJ data are implemented. The reduction for hemophilia drugs is about 30 percent. The three hemophilia drugs on the DOJ list represent about 5 percent of Medicare spending for drugs on the list and about 5 percent of the savings.

We have also analyzed the other drugs. Of the remaining 34 drugs, 2 are furnished by urologists (the largest being lupron), 4 are inhalation drugs furnished by durable medical equipment suppliers (the largest being albuterol), 2 are end-stage renal disease drugs (other than EPO) and 20 drugs are steroids, tranquilizers, antibiotics, impotence-related, AIDS-related, etc. Two of the 51 drugs are not covered under the Medicare drug benefit (and thus not paid under the average wholesale price) and another 4 have no Medicare billing codes.

Finally, we also have received a revised opinion from OGC indicating that HCFA can require carriers to use the DOJ data, even without rule making. This is because the data are characterized by DOJ as more accurately reflecting average wholesale prices.

Next Steps

HCFA will shortly send data on all the DOJ drugs to carriers. We will send them two files, both of which will be available once we release them to our carriers.

- The first file will contain the new, more accurate DOJ average wholesale price data for all but the 14 oncology and 3 hemophilia drugs. We plan to require carriers to use the data for these drugs effective October 1. Requiring the use of this data is a more aggressive move to protect Medicare spending than originally indicated in the Bliley and Stark letters.
- The second file will contain the new data for the oncology and hemophilia drugs. We will tell the carriers that we are providing this data for their information but not to act on it as of this time. Before implementing the DOJ data for oncology drugs we will comprehensively review a series of Medicare policies affecting cancer treatment in physician offices. Similarly, before implementing the DOJ data for hemophilia drugs, we will review issues about payment for their delivery. The date for implementation for the oncology and hemophilia drugs would depend on our review and analysis of the special situations for those drugs.

Under this approach, HCFA will ensure that beneficiaries have access to the drugs they need and deserve while protecting the trust fund. HCFA would achieve the bulk of savings available from the list immediately (69 percent). We will also use the DOJ price data for payment made under the

outpatient hospital prospective payment system. (About half of the drugs on the DOJ list are paid for separately under the outpatient PPS through the pass-through provision.)

HHD809-0012

Attachment: DOJ Drug List by Category

| Category | CY 1999 Data | |
|------------|------------------------|--------------------------|
| | Medicare Spending | Savings from DOJ |
| Oncology | \$298,218,671 17.1% | (\$168,972,413) 26.4% |
| Hemophilia | \$93,584,360 5.4% | (\$29,659,941) 4.6% |
| Inhalation | \$288,396,256 16.5% | (\$190,203,823) 29.7% |
| Urology | \$637,157,314 36.6% | (\$132,072,913) 20.6% |
| ESRD | \$306,404,809 17.6% | (\$82,503,176) 12.9% |
| Misc | \$119,464,591 6.9% | (\$36,283,616) 5.7% |
| | \$1,743,226,002 | (\$639,695,882) |

HHD809-0013